Biologics Program Director

Description of Duties:

Become a part of the Department that touches the lives of every American! At the Department of Health and Human Services (DHHS) you can give back to your community, state, and country by making a difference in the lives of Americans everywhere. Join HHS and help to make our world healthier, safer and better for all Americans.

FDA's Office of Regulatory Affairs (ORA), Office of Operations (OO) is searching for a Biologics Program Director (BPD). The incumbent in this position will serve as the Biologics Program Director and is responsible for overseeing and ultimately managing all of the field biologic product professional program activities and is the key point of interface with the CBER scientific, compliance and program offices in both the planning for the use of these resources as well as accountable for the field implementation of operational plans. As the BPD, the incumbent will advise the Assistant Commissioner for Operations (ACO), the Associate Commissioner for Regulatory Affairs (ACRA), and other senior FDA officials and others on all operational, scientific, regulatory and policy-making activities that affect ORA-wide programs, projects and initiatives or have an impact on development and achievement of long-range program goals.

Major duties and responsibilities include but are not limited to:

- Negotiates the multi-year field work plan covering both planned and unplanned work between ORA and the Center for Biologics Evaluation and Research (CBER) which is binding on both parties to carry out unless and until it is modified with agreement of both parties.
- Works with CBER to identify the nature, quantity and geographic location of the work that needs to be done and can be planned. These would include such diverse and critical activities as surveillance inspections, for cause inspections, import review and sample collections, and laboratory testing and applied research needs.
- Designs, develops and implements plans that provide estimates for important activities such as: for unplanned work, pre-approval inspections, investigating complaints, and required investigations of incidents that suggest Food, Drug, and Cosmetic (FD&C) Act violations and/or public health concerns.
- Recommends to the ACO and the ACRA the annual level of biological field resources to be reserved in the field device allocation for public health emergencies. Assures that as the year progresses any reserves are reprogrammed to non-emergency work when available.

Additional duties and responsibilities:

- Creates and maintains strong working relationships with high level Federal Officials, Members of Congress, Scientists, University Administrators, and industry to assess the political and institutional environment in which decisions are made and implemented.
- Serves as the senior advisor to the ORA leadership and CBER on all matters pertaining to the ORA biologics field program relating to investigational and compliance matters.
- Manages the implementation of change in the field and headquarters ORA programs in response to changes in legislation, major court decisions, budget changes and alike.

- Monitors and tracks regulatory actions and works with CBER to assure adequate coordination between the ORA, Office of the Chief Counsel (OCC) and the CBER.
- Collaborates on the development of biologics device training programs to assure that specialists in the FDA Centers and the field are trained in the same operational procedures so that regulated industry experiences uniform, consistent application of FDA regulatory standards.
- In consultation with the ACRA, Deputy Associate Commissioner for Strategic Management, and other ORA leadership develops long range strategic, scientific and tactical plans for the specialization of ORA resources including biologics investigational staff and compliance staff to meet the ORA's current and future needs.

Qualifications:

Applicants must possess a Ph.D. or equivalent in one of the following: biological sciences, chemistry, pharmacy, physical sciences, food technology, nutrition, medical science, engineering, epidemiology, veterinary medical science, or related scientific fields that provide knowledge directly related to consumer safety officer work. Up to 8 semester hours in statistics or course work that includes the principles, theory or practical application of computers or computer programming may be accepted.

ORA is seeking recognized scientific leaders with experience and knowledge of biologics product programs. Additionally, candidates should have knowledge of FDA programs and public health policies. Highly qualified candidates will have experience with management and leadership, outreach, and ability to communicate orally and in writing. They should have strong interpersonal skills in presenting recommendations and negotiating solutions to disputed recommendations, as well as the ability to think and plan strategically as they will set the course for short- and long-term food and feed policy at ORA. Multi-disciplinary experience is a plus. Candidates must be able to function well independently as well as in a team setting, able to manage and adapt to multiple complex priorities. handle long-term projects and adapt to ambiguity.

Location: Rockville, Maryland

Salary: Salary is commensurate with qualifications and experience. A full Federal benefits package is also available including: leave, health and life insurance, retirement, long term care insurance, and Thrift Savings Plan (401K equivalent).

To apply: Send letter of interest addressing your experience in the major duties and responsibilities of the position, CV and bibliography, SF-50 for current federal employees only, and a PhD transcript (with foreign credentials evaluation if applicable) to BPD Recruitment Committee, ORAExecutiveRecruitment@fda.hhs.gov.

CLOSING DATE FOR APPLICATIONS IS: August, 14, 2016

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